

APR 13 2005

Customer No. 27061

Patent
Attorney Docket No. GEMS8081.041

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Brinsfield et al.
Serial No. : 09/689,374
Filed : October 12, 2000
For : Mobile Clinical Information System
Group Art No. : 3626
Examiner : Porter, R.

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

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RESPONSE TO OFFICE ACTION
MAILED JANUARY 13, 2005

Dear Sir:

Responsive to the Office Action mailed January 13, 2005, Applicant requests reconsideration based on the remarks set forth below. By rule, a complete listing of the claims as currently pending precedes the remarks.

Copy of Applicant's response
filed March 14, 2005

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Brinsfield et al.

S/N: 09/689,374

In the Claims

1. (Original) A wireless bi-directional portable patient monitor comprising:
 - a communication interface to receive patient data from a wireless local area network (WLAN) within a medical care facility and transmit care parameters as needed to the WLAN in response thereto;
 - a processor connected to the communication interface to process the patient data and the care parameters;
 - a display connected to the processor to display the processed patient data in human discernable form; and
 - an input device connected to the processor to allow a change in the care parameters by a health care provider.
2. (Original) The portable patient monitor of claim 1 wherein the processor decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN.
3. (Original) The portable patient monitor of claim 1 wherein the portable patient monitor is a primary monitoring device.
4. (Original) The portable patient monitor of claim 1 wherein the processor processes the patient data to display ECG and vital sign data for a selected patient.
5. (Original) The portable patient monitor of claim 1 wherein the communication interface is compatible with an existing WLAN.
6. (Original) The portable patient monitor of claim 1 wherein the portable patient monitor is packaged within a housing that is transportable on a health care provider for extended periods.
7. (Original) The portable patient monitor of claim 6 having a length of approximately 7" (17.8 cm), a width of approximately 3.75" (9.5 cm), and a thickness of approximately 1.0" (2.54 cm).

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

8. (Original) The portable patient monitor of claim 1 wherein the processor is programmed to allow alarm silencing of a bedside monitor, and admit and discharge patients.

9. (Original) The portable patient monitor of claim 1 wherein the processor is programmed to allow adjustment of alarm parameter violation limits.

10. (Original) The portable patient monitor of claim 1 further comprising a speaker and microphone, and wherein the processor is programmed to process data to permit voice-over-internet protocol (IP) transfer.

11. (Original) The portable patient monitor of claim 1 further comprising a bar code scanning module and a bar code scanner, and wherein the processor is programmed to receive and compare patient data with data obtainable from a centralized database that includes pharmaceutical and patient bar codes to ensure dosage accuracy, and doctor orders.

12. (Original) The portable patient monitor of claim 1 wherein the processor is further programmed to interface with non-proprietary networked systems.

13. (Original) The portable patient monitor of claim 12 wherein the processor is further programmed to interface with infusion pumps and ventilators.

14. (Original) The portable patient monitor of claim 1 wherein the processor is further programmed to receive patient reports and diagnostic analyses prepared at other locations in the medical care facility to provide the health care provider with the patient reports and diagnostic analyses in real time.

15. (Original) The portable patient monitor of claim 1 further comprising a PDA module to provide PDA functions to the health care providers.

16. (Previously Presented) The portable patient monitor of claim 15 wherein the PDA functions at least include a scheduler, reminders, and to-do lists.

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

17. (Original) The portable patient monitor of claim 1 further comprising a microphone and a digital audio recorder module to input a record of patient medical events by the health care provider.

18. (Original) A mobile clinical information management system to decentralize patient monitoring comprising:

a portable patient monitor having a processor connected to a communication interface to receive and process patient data and to process and transmit care parameters, a display to display the patient data, and an input device to change the patient care parameters, the portable patient monitor having a configuration to allow wireless transport on a health care provider for extended periods;

a plurality of bedside patient monitors to connect to a plurality of patients and transmit patient data;

a WLAN coupled to the plurality of bedside patient monitors and the portable patient monitor.

19. (Original) The system of claim 18 further comprising a plurality of portable patient monitors, each portable patient monitor assigned to a given number of patients.

20. (Original) The system of claim 18 wherein the processor further:
decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN; and
processes the patient data to display ECG and vital sign data for a selected patient on the portable patient monitor.

21. (Original) The system of claim 18 wherein the portable patient monitor is a primary monitoring device and wherein a communication interface of the portable patient monitor is compatible with an existing WLAN.

22. (Original) The system of claim 18 wherein portable patient monitor has a length of approximately 7" (17.8 cm), a width of approximately 3.75" (9.5 cm), and a thickness of approximately 1.0" (2.54 cm).

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

23. (Original) The system of claim 18 further comprising a speaker and microphone, and wherein the processor is programmed to:

- allow alarm silencing of a bedside monitor;
- admit and discharge patients;
- adjust alarm parameter violation limits; and
- process data to permit voice-over-internet protocol (IP) transfer.

24. (Original) The system of claim 18 further comprising:

a bar code scanning module and a bar code scanner and wherein the processor is programmed to receive patient data encoded in a patient wristband, and to compare patient data with data obtainable from pharmaceutical bar codes and a centralized database to check dosage accuracy and compliance with doctor orders;

wherein the processor is further programmed to interface with infusion pumps and ventilators, and to receive patient reports and diagnostic analyses prepared at remote locations in the medical care facility to provide the health care provider with the patient reports and diagnostic analyses in real time.

25. (Original) The system of claim 18 wherein the portable patient monitor includes a PDA module having PDA functions that include a scheduler, reminders, and to-do lists, and further comprises a microphone and a digital audio recorder module to record an audio input by the health care provider into the microphone and record patient medical events.

26. (Original) A computer program residing in memory of a portable patient monitor to cause a processor to:

- remotely interface to a WLAN to acquire any patient alarms;
- sound an alarm if a patient alarm occurs;
- allow user silencing of the alarm at the portable patient monitor and at a bedside monitor; and
- display patient data.

27. (Original) The computer program of claim 26 wherein the computer program further causes the processor to:

- periodically check a recharged battery charge; and

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

display a warning if the rechargeable battery charge is low.

28. (Original) The computer program of claim 26 wherein the computer program further causes the processor to allow user adjustment of alarm parameter violation limits.

29. (Original) The computer program of claim 26 wherein the computer program further causes the processor to relay patient admission and discharge information to the WLAN.

30. (Original) The computer program of claim 26 wherein the computer program further causes the processor to process audio data from a health care provider to record medical history of a patient.

31. (Original) The computer program of claim 26 wherein the computer program further causes the processor to scan a bar code from a patient ID and compare data obtained therefrom with data on the patient from a main patient database to ensure proper medical treatment.

Copy of Applicant's response
filed March 14, 2005

6

Brinsfield et al.

S/N: 09/689,374

REMARKS

Claims 1-31 are pending in the present application. In the Office Action mailed January 13, 2005, the Examiner rejected claims 1-7, 9, 12, 14, and 18-22 under 35 U.S.C. §102(e) as being anticipated by Maschke et al. (USP 6,221,012). The Examiner next rejected claim 13 under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. Claims 11 and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. and Gombrich (USP 4,857,716). Claims 8, 26, and 28-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. and Fuchs et al. (USP 5,788,646). Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. and Ballantyne (USP 5,867,821) and further in view of Official Notice. Claims 15-17 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al. in view of Ballantyne. Claim 23 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Ballantyne, Official Notice, and further in view of Fuchs et al. Claims 27 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Fuchs et al., and further in view of Gombrich. Claim 30 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maschke et al., Fuchs et al., and further in view of Ballantyne.

Applicant appreciates the withdrawal of the rejection of claim 16 under 35 U.S.C. §112, second paragraph.

The Examiner rejected claims 1-7, 9, 12, 14, and 18-22 under 35 U.S.C. §102(c) as being anticipated by Maschke et al. (hereinafter Maschke). However, Maschke does not anticipate claim 1 for three distinct reasons.

First, in order to anticipate claim 1, Maschke must teach a bi-directional portable patient monitor having a communication interface to receive patient data from a WLAN within a medical care facility and transmit care parameters as needed to the WLAN in response thereto. Although the Examiner cites col. 3, lns. 21-44 of Maschke to support such a teaching, Maschke fails to teach any use of a WLAN, let alone one as set forth in the claims. Maschke states that a "portable monitor 102 is detachably coupled to and acquires physiological data signals from a plurality of data acquisition modules." Col. 3, lns. 22-25. Maschke teaches that the use of detachably coupling as used in its teachings "is intended to include any manner of communicating the acquired data signals to monitor 102, such as a wireless communication link." Col. 3, 39-44. While Maschke suggests that coupling the portable monitor to data acquisition modules may include a wireless communication link, there is no teaching of any communication link other than

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

a wired communication link. That is, there is no teaching of any alternative embodiment that enables a wireless communication link. At best, there is only a suggestion that a wireless communication link may be used. Furthermore, Applicant does not believe that such a wireless communication link constitutes a WLAN as described in the previous response and as presently claimed. At best, Maschke suggests a point-to-point wire connection between a portable monitor and each data acquisition module connected thereto. Replacing the wires with a wireless communication link results in a wireless point-to-point connection between the portable monitor and each data acquisition module. One skilled in the art would not recognize such a wireless point-to-point connection as a WLAN.

Second, Maschke does not teach a bi-directional communication interface that receives patient data from a WLAN and transmits care parameters as needed to the WLAN in response to patient data received from the WLAN. Even though Maschke fails to teach a WLAN, for purposes of responding to this rejection, references to the WLAN will refer to the coupling of the portable monitor to a data acquisition module through some wireless means. Maschke teaches DMA channels 344a, 344b for communicating with the data acquisition modules that "send commands and timing information to the [data acquisition modules], and receive data and status from them." Col. 9, lns. 37-44. However, Maschke fails to teach the transmission of care parameters to the WLAN by the portable monitor. That is, while Maschke teaches receiving data and status from the DMA channels, the teachings of sending commands and timing information to the data acquisition modules over the DMA channels are not tantamount to transmitting care parameters to the WLAN. One skilled in the art would not recognize that the commands and timing information sent to the data acquisition modules are care parameters as set forth in the claims.

Third, Maschke fails to teach transmitting the care parameters to the WLAN as needed in response to patient data received from the WLAN. As stated above, there is no teaching of care parameters being sent from the portable monitor to the WLAN. Likewise, since no care parameters are taught as being sent to the WLAN, there is no teaching of transmitting the care parameters to the WLAN as needed in response to patient data received from the WLAN. In fact, there is no teaching of any action in response to the patient data received from the WLAN.

For at least these reasons, claim 1 is deemed patentably distinct from the art of record. As such, claims 2-17 are also deemed patentably distinct pursuant to the chain of dependency.

Although claims 2-17 are deemed patentably distinct from the art of record pursuant to the chain of dependency, Applicant wishes to discuss the rejection of some of these claims.

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

With respect to claim 2, the Examiner stated that Maschke teaches a processor that decodes the patient data to process and display the patient data and encodes the care parameters to transmit the care parameters to the WLAN. As stated above, Maschke fails to teach the transmission of care parameters to the WLAN. Likewise, Maschke fails to teach encoding of any parameters for transmission to the WLAN.

Claim 8 calls for the processor to be programmed to allow alarm silencing of a bedside monitor. The Examiner rejected claim 8 under 35 U.S.C. §103(a) as being unpatentable over Maschke in view of Fuchs et al. (hereinafter Fuchs). The Examiner stated that Maschke does not expressly disclose that the patient monitoring system includes a processor to silence a patient's bedside alarm and that Fuchs discloses that patient monitoring systems often enable remote silencing of bedside patient alarms. While some patient monitoring systems often enable remote silencing of bedside alarms, the references do not teach a bedside monitor having an alarm. Specifically, pod 150 is taught to optionally include memory for storing alarm limits. Maschke, col. 11, lns. 58-60. However, alarm limits stored in memory do not constitute an alarm. Therefore, pod 150 is not a bedside monitor having an alarm. There is no teaching or suggestion in the prior art of a bedside monitor having an alarm. Although Fuchs discusses remote silencing of bedside patient alarms, there is no suggestion or motivation to combine the references to include an alarm on a data acquisition module/bedside monitor to remotely silence.

With regard to claim 10, the Examiner took Official Notice that VOIP was well known in the art and that, therefore, it would have been obvious to one of ordinary skill in the art to modify the patient monitor of Maschke and Ballantyne to permit VOIP. However, in addition to Applicant's remarks in the previous communication, Applicant wishes to add the following remarks.

The Examiner stated in response to Applicant's argument that the Examiner's conclusion of obviousness was based on hindsight reasoning that, in the present case, "the Examiner has relied upon the reasoning of one of ordinary skill in the art and motivation pulled from one or more of the cited references to support the holding of obviousness." Office Action, p. 19. The Examiner supplied Gallant et al. and Kaffine et al. in support of the conclusion that VOIP was known in the art. Applicant does not dispute that VOIP can be found in Gallant and Kaffine. However, despite the fact that VOIP is found in Gallant and Kaffine, there is no teaching or suggestion in the prior art used to reject claim 10 that calls for the portable patient monitor comprising a speaker, a microphone, and programming the processor to process data to permit voice-over-internet protocol transfer, and at the time of the invention, Applicant contends that the

Copy of Applicant's response
filed March 14, 2005

Brinsfield et al.

S/N: 09/689,374

use of VOIP was not well known in the art. "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levensgood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)." MPEP § 2143.01 (emphasis added).

While the Examiner supplied Gallant et al. and Kaffine et al. in support of the conclusion that VOIP was known before Applicant's filing date, neither reference is used to reject claim 10 under obviousness. The Examiner supplied evidence that VOIP was well known; however, there is no teaching, suggestion, motivation, or objective reason in the prior art used in rejecting claim 10 that supports modification of the prior art to meet the claimed invention. That is, there is no motivation to include, use, or combine the prior art to meet the claimed invention having VOIP merely because VOIP was well known. That VOIP was well known is irrelevant absent some objective reason to combine or modify the prior art to meet the claimed invention. There is no objective reason to combine VOIP with the prior art to meet the claimed invention absent hindsight. As such, a prima facie case of obviousness has not been met.

The Examiner rejected claim 18 under 35 U.S.C. §102(e) as being anticipated by Maschke. Applicant respectfully disagrees.

Claim 18 calls for a portable patient monitor having a processor connected to a communication interface to receive and process patient data and to process and transmit care parameters. That is, the communication interface both receives patient data and transmits care parameters. As indicated above, Maschke fails to teach the transmission of care parameters over the same communication interface that receives patient data. Maschke does not teach transmitting care parameters to the data acquisition modules. As such, there is no teaching that the communication interface that receives patient data also transmits the care parameters. Furthermore, as stated above, Maschke fails to teach a WLAN.

For at least these reasons, claim 18 is deemed patentably distinct from the art of record. As such, claims 19-25 are also deemed patentably distinct pursuant to the chain of dependency.

Although claims 19-25 are deemed patentably distinct from the art of record pursuant to the chain of dependency, Applicant wishes to discuss the rejection of some of these claims.

Copy of Applicant's response
filed March 14, 2005

10

Brinsfield et al.

S/N: 09/689,374

Claim 20 calls for the processor to encode care parameters to transmit the care parameters to the WLAN. As stated above, Maschke fails to teach a WLAN. Also, as stated above, Maschke fails to teach transmission of care parameters to the WLAN.

Claim 23 calls for the processor programmed to process data to permit voice-over-internet protocol (IP) transfer. As stated above with respect to claim 10, a prima facie case of obviousness is not met because there is no teaching, suggestion, motivation, or objective reason in the prior art used in rejecting claim 23 that supports modification of the prior art to meet the claimed invention. Gallant and Kaffine, are *only* used to support what was well known to one skilled in the art and are *not* used to reject claim 23.

Further, claim 23 calls for the processor programmed to allow alarm silencing of a bedside monitor. As stated above, the data acquisition modules do not contain alarms. Since the combination of the prior art fails to suggest each element of claim 23, a prima facie case of obviousness has not been met.

The Examiner rejected claim 26 under 35 U.S.C. §103(a) as being unpatentable over Maschke and Fuchs. Applicant respectfully disagrees.

Applicant incorporated the remarks set forth above regarding the failure of Maschke to teach a WLAN. Furthermore, claim 26 calls for remotely interfacing a WLAN to acquire any patient alarms. Besides not teaching a WLAN, Maschke also fails to teach any alarms acquirable on any wired or wireless communication link between the portable monitor and the data acquisition modules. As stated above, the data acquisition modules do not have alarms. The Examiner stated that "it would have been obvious to one of ordinary skill in the art to modify the method/system of Maschke with the teaching of Fuchs to provide alarms when patients experience emergencies and to allow the user to remotely silence patient bedside alarms." Office Action, pp. 9-10. Maschke teaches that the portable monitor includes an alarm, but no bedside monitor is taught to have an alarm. See col. 6, lns. 59-64. The prior art does not suggest adding an alarm to a data acquisition module so that when the portable monitor is connected thereto, the alarm can be turned off. The Examiner has not provided any support in the prior art for a motivation to include an alarm in any data acquisition module.

Further, since no alarm is generated by the data acquisition modules, there is no alarm on the "WLAN" to acquire. There is no teaching or suggestion in the prior art to remotely interface to a WLAN to acquire any patient alarms. Furthermore, since the data acquisition modules do not have alarms, the prior art does not teach or suggest allowing user silencing of the alarm at the

Copy of Applicant's response
filed March 14, 2005

11

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Brinsfield et al.

S/N: 09/689,374

portable patient monitor and at a bedside monitor because there is no teaching of a bedside monitor having an alarm in the prior art.

For at least these reasons, claim 26 is deemed patentably distinct from the art of record. As such, claims 27-31 are also deemed patentably distinct pursuant to the chain of dependency.

Therefore, in light of at least the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-31.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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Dated: March 14, 2005
Attorney Docket No.: GEMS8081.041

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Copy of Applicant's response
filed March 14, 2005

12